

Attorney's Docket No. 028870-057

Patent

19/ Declaration
1.132

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Guy LaTorre et al.

Application No.: 09/488,202

Filed: January 19, 2000

For: COMPOSITIONS AND METHODS
FOR TREATING NAILS AND
ADJACENT TISSUES

Group Art Unit: 1615

Examiner: R. Bennett

DECLARATION UNDER 37 C.F.R. § 1.132Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, David C. Greenspan, hereby state as follows:

1. I am an inventor in the above-identified patent application.
2. A 5 leg experiment was started on the efficacy of HA precipitation onto human fingernails by method of exposing the fingernails to Tris buffer solution containing Bioglass® and a 100ppm CA solution as a positive control. All experimental legs and conclusions are listed below.
- * 3. Leg #1 = 1 Fingernail clipping was exposed to 200ml of Tris buffer with 0.3gr 45s5 <20um Bioglass® Particulate for a time frame of 20 hrs. with samples done in duplicate. After exposure the samples were removed from the solution and placed into a drying oven @ 45°C for 1hr. to dry. Then FTIR analysis was performed on the samples to see if HA had precipitated on the surface.
- * 4. Leg #2 = 1 Fingernail clipping was exposed to 200ml of Tris buffer with 0.3 gr 45s5 200-500 um Bioglass® Particulate for a time frame of 20 hrs. with samples done in duplicate. After exposure the samples were removed from the solution and placed into a drying oven @ 45°C for 1 hr. to dry. Then FTIR analysis was performed on the samples to see if HA had precipitated on the surface.

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5. Leg #3 = 1 Fingernail clipping was exposed to 200 ml of Tris buffer with 0.3gr bioinert 60s <20 um Bioglass® Particulate for a time frame of 20 hrs. with samples done in duplicate. After exposure the samples were removed from the solution and placed into a drying oven @ 45°C for 1 hr to dry. Then FTIR analysis was performed on the samples to see if HA had precipitated on the surface.

6. Leg #4 = 1 fingernail clipping was exposed to a 100ppm Ca solution (Made by mixing 1gr of CaNO3 to 400 ml of Tris buffer on a stir plate for 15 min.) for a time frame of 20 hrs. with samples done in duplicate. After exposure the samples were removed from the solution and placed into a drying oven @ 45°C for 1 hr. to dry. Then FTIR was performed on the samples to see if HA had precipitated on the surface.

7. Leg #5 - 1 Fingernail clipping was exposed to Tris Buffer solution for a time frame of 20 hrs. with samples done in duplicate. After exposure the samples were removed from the solution and placed into a drying oven @ 45°C for 1 hr. to dry. Then FTIR analysis was preformed on the samples to se if HA had precipitated on the surface.

8. Conclusions:

- bioglass*
- * Leg #1: FTIR analysis showed that a HA layer had precipitated onto the surface of the nail.
 - * Leg #2: FTIR analysis showed that a HA layer had precipitated onto the surface of the nail but not as pronounced as leg #1 in this experiment.
 - Leg #3: FTIR analysis showed no HA had precipitated onto the surface of the nail.
 - Leg #4: FTIR analysis showed no HA had precipitated onto the surface of the nail.
 - Leg #5: FTIR analysis showed no HA had precipitated onto the surface of the nail.

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9. Attached are Figures 1-12, illustrating the results of the above experiments.

10 I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

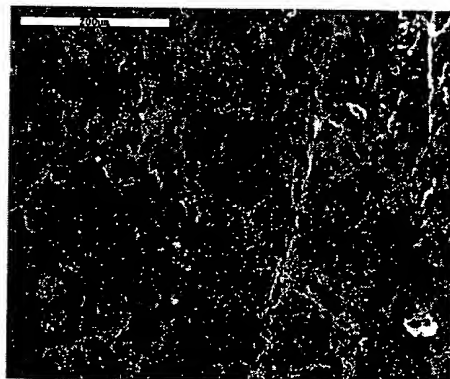
Name:

David C. Greenspan

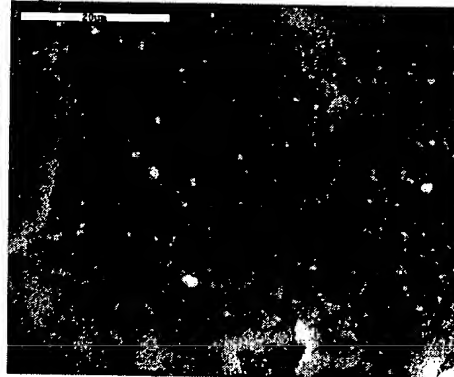
Date:

7/3/01

Bioactive Glasses in Nail Care Applications **Experiment #3(soak): SEM Analysis**



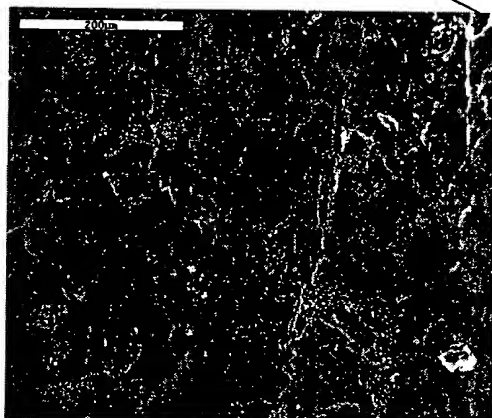
SEM @ 200X
Unreacted nail surface



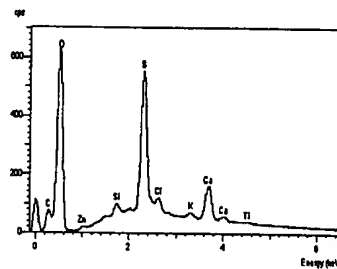
SEM @ 2000x
Unreacted nail surface

Figure 1

Bioactive Glasses in Nail Care Applications **Experiment #3(soak): SEM/EDS Analysis**



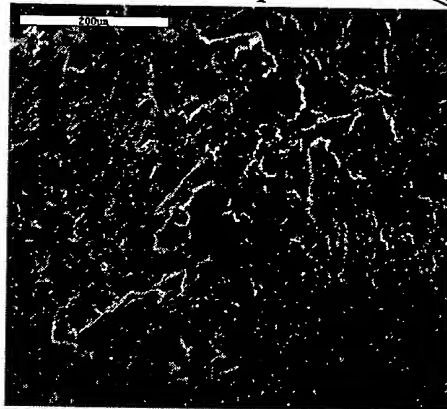
SEM @ 200x
Unreacted nail surface



EDS @ 200x
Unreacted nail surface

Figure 2

Bioactive Glasses in Nail Care Applications
Experiment #3(soak): SEM Analysis



SEM @ 200x

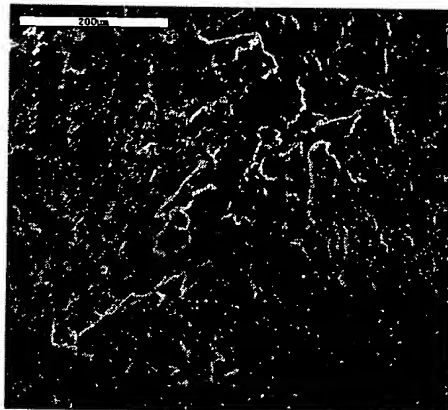


SEM @ 2000x

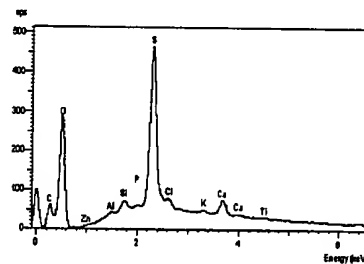
Nail surface reacted for 20hrs.
In tris buffer only

Figure 3

Bioactive Glasses in Nail Care Applications
Experiment #3(soak): SEM/EDS Analysis



SEM @ 200x



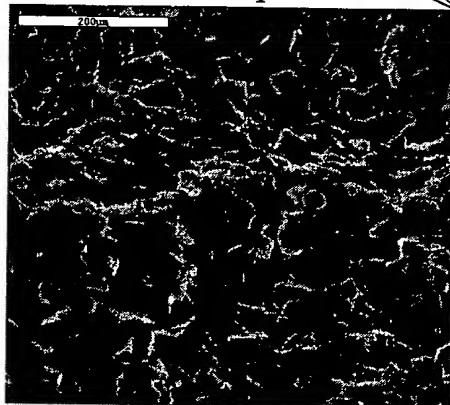
EDS @ 200x

Nail surface reacted for 20hrs.
In tris buffer only

Figure 4

Bioactive Glasses in Nail Care Applications

Experiment #3(soak): SEM Analysis



SEM @ 200x



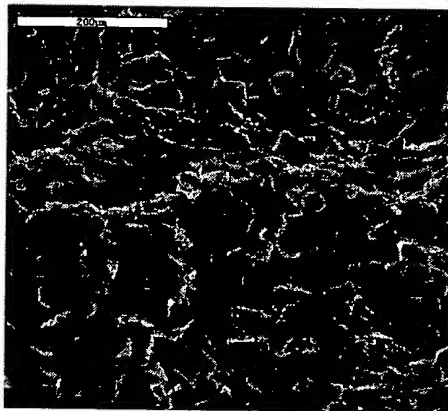
SEM @ 2000x

Nail surface reacted for 20hrs.
In tris buffer & 100 ppm Calcium

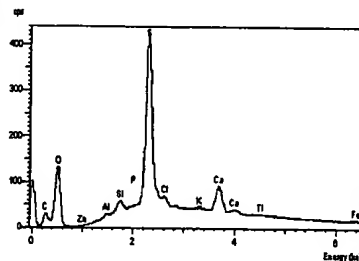
Figure 5

Bioactive Glasses in Nail Care Applications

Experiment #3(soak): SEM/EDS Analysis



SEM @ 200x

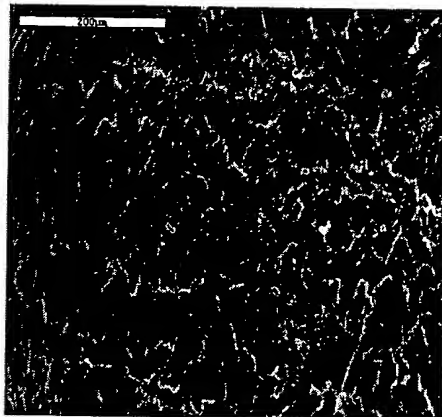


EDS @ 200x

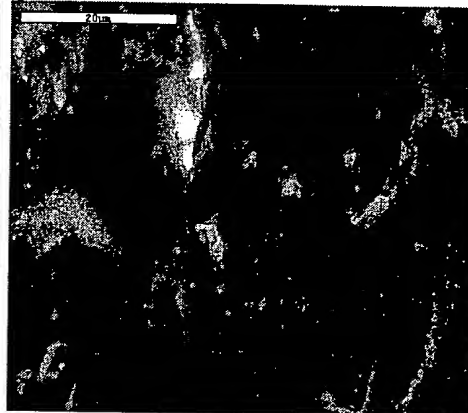
Nail surface reacted for 20hrs.
In tris buffer & 100 ppm Calcium

Figure 6

Bioactive Glasses in Nail Care Applications **Experiment #3(soak): SEM Analysis**



SEM @ 200x

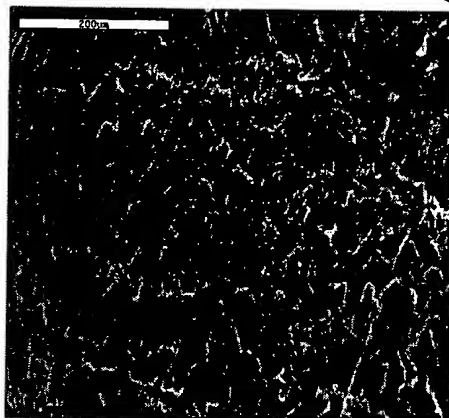


SEM @ 2000x

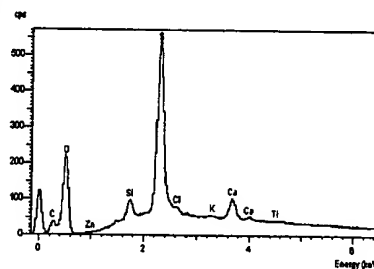
Nail surface reacted for 20hrs.
 In tris buffer & 60s Bioglass

Figure 7

Bioactive Glasses in Nail Care Applications **Experiment #3(soak): SEM/EDS Analysis**



SEM @ 200x



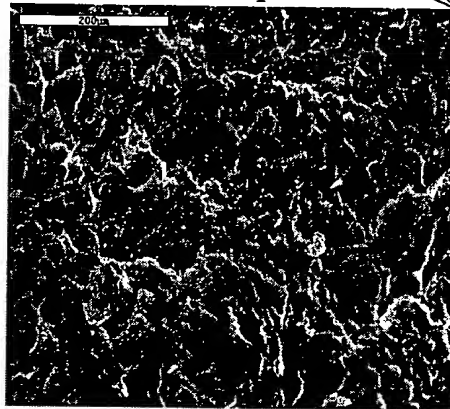
EDS @ 200x

Nail surface reacted for 20hrs.
 In tris buffer & 60s Bioglass

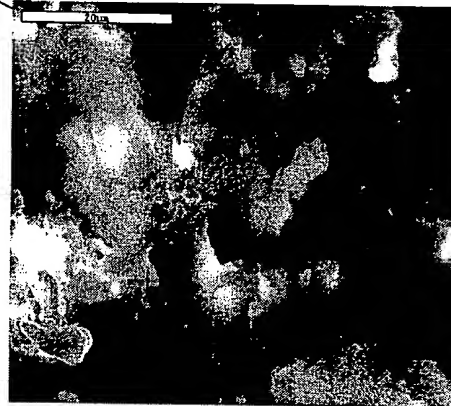
Figure 8

Bioactive Glasses in Nail Care Applications

Experiment #3(soak): SEM Analysis



SEM @ 200x



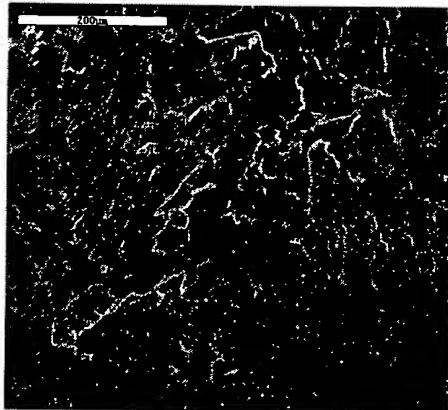
SEM @ 2000x

Nail surface reacted for 20hrs.
In tris buffer & 200-500 μm Bioglass

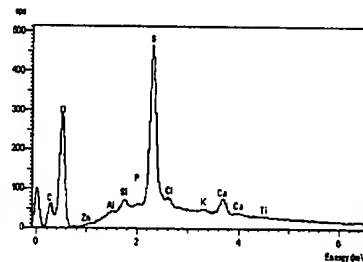
Figure 9

Bioactive Glasses in Nail Care Applications

Experiment #3(soak): SEM/EDS Analysis



SEM @ 200x



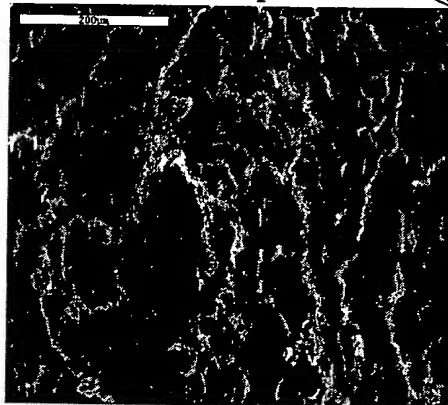
EDS @ 200x

Nail surface reacted for 20hrs.
In tris buffer & 200-500 μm Bioglass

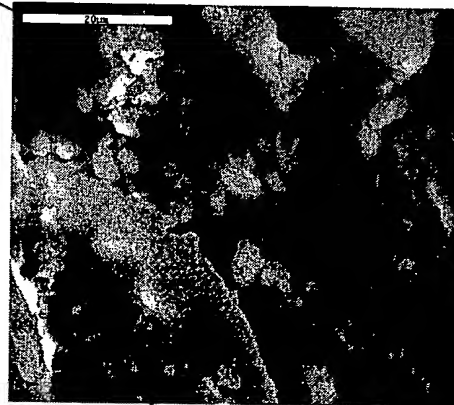
Figure 10

Bioactive Glasses in Nail Care Applications

Experiment #3(soak): SEM Analysis



SEM @ 200x



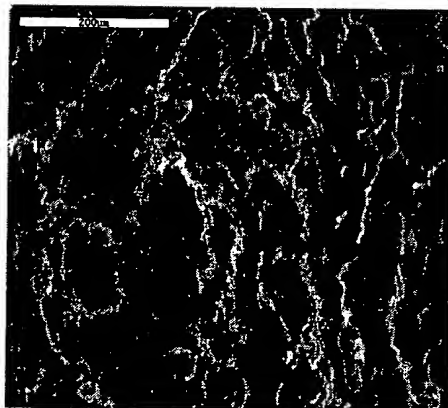
SEM @ 2000x

Nail surface reacted for 20hrs.
In tris buffer & <20 um Bioglass

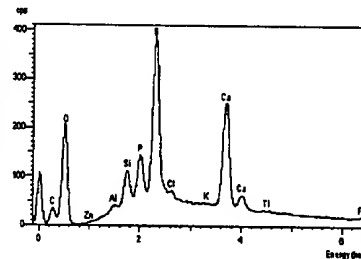
Figure 11

Bioactive Glasses in Nail Care Applications

Experiment #3(soak): SEM/EDS Analysis



SEM @ 200x



EDS @ 200x

Nail surface reacted for 20hrs.
In tris buffer & <20 um Bioglass

Figure 12